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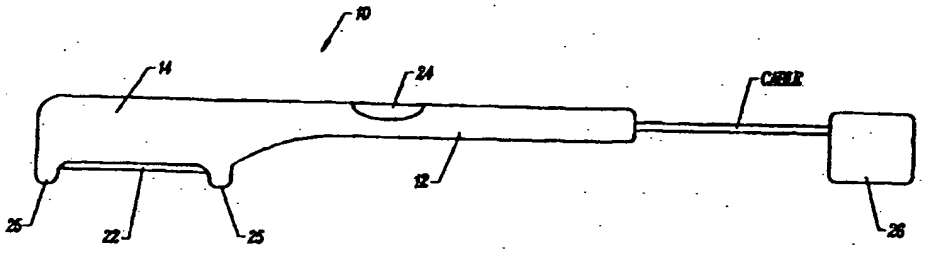
(54) Title: APPARATUS FOR TREATING CHONDROMALICIA



(57) Abstract

A thermal energy delivery apparatus (10) has a probe means (12) including a distal end and a proximal end. A first electrode means (22) is positioned at the distal end of the probe means. The first electrode (22) means is configured to deliver sufficient thermal energy to a fibrillated cartilage surface to reduce a level of fibrillation of the fibrillated cartilage surface. A cabling means is coupled to the proximal end of the probe means.

APPARATUS FOR TREATING CHONDROMALICIA

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to a method and apparatus for treating chondromalacia, and more particularly to a method and apparatus that treats chondromalacia with minimal disruption of the cartilage bed of the knee.

Description of Related Art

The normal function of joints in humans depends on the distribution of relatively large forces across the body surfaces. In diarthrodial joints the magnitude of the joint forces reaches levels four to seven times body weight. These forces applied to joints are dispersed by articular cartilage. Cartilage function occurs via a highly organized extracellular matrix maintaining a fixed charge density and possessing a high affinity for water.

Normal articular cartilage consists of an assembly of large and small proteoglycans, collagens, hyaluronic acid and glycoproteins. These matrix macromolecules originate from chondrocytes localized in a nonrandom pattern through the cartilage matrix. In normal joints, chondrocytes do not proliferate; dividing chondrocytes indicate a change in cartilage homeostasis, either as regeneration or attempted repair.

Chondromalacia occurs when cartilage beds in joints become worn and strands of cartilage distended away from their respective cartilage beds and extend into the joint capsule. The cartilage surface becomes visibly disrupted, fissured and fibrillated. This has deterious effects on the mechanical properties of articular cartilage. This distension has been associated with knee pain. Treatment to date has included surgical intervention. In one arthroscopic procedure, a shaver is introduced through an arthroscope and is used to remove

These and other objects of the invention are achieved in a thermal energy delivery apparatus that has a probe means including a distal end and a proximal end. A first electrode means is positioned at the distal end of the probe means. The first electrode means is configured to deliver sufficient thermal energy to a fibrillated cartilage surface to reduce a level of fibrillation of the fibrillated cartilage surface. A cabling means is coupled to the proximal end of the probe means.

In one embodiment of the invention, an apparatus is configured to be positioned adjacent to a fibrillated cartilage joint surface. A probe means has a distal end and a proximal end. An insulator means has a first surface and a second surface. A first electrode means is positioned on the first surface of the insulator. The first electrode means has a first thermal energy delivery surface configured to deliver sufficient thermal energy to a plurality of cartilage strands coupled to the fibrillated cartilage joint surface to reduce a level of fibrillation of surface. A second electrode means is positioned on the second surface of the insulator. A cable means is coupled to the proximal end of the probe means.

In another embodiment, a method modifies a geometry of a fibrillated cartilage surface. A thermal energy delivery device is provided and includes a probe means with a distal end and a thermal energy delivery surface. A thermal energy source is also provided and coupled to the thermal energy delivery surface. The thermal energy delivery surface is positioned adjacent to the fibrillated cartilage surface in a non-contacting position. Sufficient thermal energy is delivered from the thermal energy delivery surface to reduce a level of fibrillation of the fibrillated cartilage surface.

The method and apparatus of the present invention can also be used to decrease the level of irregularity of an irregular cartilage surface.

The apparatus of the present invention may also include a sensor means positioned at the distal end of the probe means. A comparator means is provided and compares a measured temperature value at the sensor means with a predetermined temperature value. The comparator means generates a disabling

Figure 7 is a perspective view of the apparatus of the present invention including a rectangularly shaped electrode.

Figure 8 illustrates a perspective view of the apparatus of the present invention with electrodes formed on peripheral faces of the insulator.

Figure 9 is a cross-sectional view of the apparatus of Figure 8 taken along the lines 9-9.

Figure 10 is a perspective view of an electrode used with the apparatus of the present invention that is formed at a peripheral surface of the insulator and defines an interior non-conducting region.

Figure 11 is a perspective view of a toroidal electrode used with the apparatus of the present invention and defines an interior non-conducting region.

Figure 12 is a perspective view of a non-circular toroidal electrode used with the apparatus of the present invention and defines an interior non-conducting region.

Figure 13 is a perspective view of a segmented electrode used with the apparatus of the present invention.

Figure 14 is a perspective view of a segmented toroidal electrode used with the apparatus of the present invention.

Figure 15 is a perspective view of a flexible probe used with the apparatus of the present invention.

Figure 16 is a block diagram illustrating a feedback system useful to control the temperature of electrodes of the present invention.

Figure 17 illustrates a circuit useful to implement the feedback system of Figure 16.

DETAILED DESCRIPTION

As shown in Figure 1, a thermal energy delivery apparatus 10 is configured to be positioned adjacent to, but spaced apart from a joint surface. Included is a probe 12 with a distal end 14, a first electrode 22 and a second electrode 24. Electrodes 22 and 24 can be operated in bipolar or monopolar.

surfaces. The present invention is also used to treat irregular joint surfaces, where there are peaks and valleys, and create a less irregular joint surface. In certain embodiments, the irregular joint surface becomes a smooth joint surface.

A first plurality of cartilage strands 34 are coupled to first cartilage bed 30 and have become dislodged and dangle in joint surface 28. A second plurality of cartilage strands 36 are connected to second cartilage bed 32. Second plurality of cartilage strands 36 have also become dislodged and dangle in joint surface 28.

In one embodiment of the invention, a method is provided that modifies a geometry of a fibrillated cartilage surface. Sufficient thermal energy is delivered from first electrode 22 or second electrode 24 at different times to reduce a level of fibrillation of the fibrillated cartilage joint surface. In various embodiments of the invention, sufficient thermal energy is delivered electrode 22 or 24 to, (i) change the fibrillated cartilage surface to a smooth or smoother surface, (ii) reduce a level of fibrillation of the fibrillated cartilage surface, (iii) cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to create a smoothened cartilage surface, (iv) cause at least a portion of a plurality of cartilage strands coupled to the fibrillated cartilage surface to melt onto the fibrillated cartilage surface or (v) melt at least a portion of a plurality of cartilage strands to create a smoothened cartilage surface.

First electrode 22 has a first thermal energy delivery surface configured to deliver thermal energy to cartilage strands 34 and second electrode 24 has a second thermal energy delivery surface configured to deliver thermal energy to cartilage strands 36. Thermal energy includes but is not limited to RF, microwave, resistive heating, ultrasound, coherent or incoherent light and a thermal jet source. By delivering the appropriate amount of thermal energy to joint surface 28, strands 34 and 36 move out of joint surface 28 and the surfaces of cartilage beds 30 and 32 are smoothened. Additionally, delivered thermal energy can remove some or substantially all of cartilage strands 34 and 36 from joint surface 28. The delivery of thermal energy physically smooths the surface

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electrodes 22 and 24. Distal end 14 can pivot, be hinged, be articulated, or made of a shaped memory metal, and the like, in order to enable first and second electrodes 22 and 24 to follow the contours of joint surface 28.

As shown in Figure 5, first and second electrodes 22 and 24 can be operated in a bipolar mode. This concentrates the flow of RF energy between first and second electrodes 22 and 24 and diverts direct RF energy flow away from cartilage beds 30 and 32. RF energy which is directed between first and second electrodes 22 and 24 heats up fluids within joint surface 28 and provides a more controlled delivery of energy to cartilage strands 34 and 36. RF ablation of cartilage beds 30 and 32 is reduced.

First and second electrodes 22 and 24 can have a variety of different geometric configurations. As illustrated in Figure 6, first and second electrodes 22 and 24 are symmetrically shaped with radiused edges Elimination of sharp edges at an electrode surface reduce the creation of hot spots of thermal energy delivered to a site. In Figure 7, first and second electrodes 22 and 24 have rectangular geometries with non-radiused edges. First and second electrodes 22 and 24 can each have different sizes and geometries. First and second electrodes 22 and 24 can be mirror images of each other or they can be different.

Referring now to Figure 8, first and second electrodes 22 and 24 are formed on a periphery of insulation surfaces 18 and 20 respectively. In this embodiment, each electrode 22 and 24 defines a first and a second non-conducting region 38 and 40 on an insulator surface 18 and 20 within an interior of first and second electrodes 18 and 20. Non-conducting regions 38 and 40 can be the actual surface of insulator 16, or may be additional structures, each with a non-conducting surface, that are formed on insulation surfaces 18 and 20.

First and second sensors 42 and 44 can be provided and associated with first and second electrodes 22 and 24 to measure temperature and/or impedance. First and second sensors 42 and 44 are positioned on a surface of first and second electrodes 22 and 24, on a surface of probe 12, on non-conducting

cartilage strands 34 and 36. A monitor 56 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value a disabling signal 48 is transmitted to thermal energy source 26, ceasing further delivery of thermal energy to first and second electrodes 22 and 24. If measured impedance is within acceptable limits, energy continues to be applied. During the application of thermal energy to cartilage strands 34 and 36, sensor 42 measures the temperature at the surface of sensor 42. A comparator 50 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 50 sends a signal to thermal energy source 26 to continue sending thermal energy, to increase or decrease the level of delivered thermal energy, or to cease delivery of thermal energy.

An output 52 from temperature comparator 50 can be input to thermal energy source 26 to regulate the amount of power delivered. Output 54 from impedance monitor 56 can be input to control the temperature at joint surface 28.

Referring now to Figure 17, thermal energy source 26 is coupled to first and second electrodes 22 and 24 and apply a biologically safe voltage to cartilage strands 34 and 36. In the embodiment illustrated in Figure 11, apparatus 10 is represented as a bipolar ablation device. First and second electrodes 22 and 24 are connected to a primary side of transformer windings 58 and 60. The common primary windings 58 and 60 are magnetically coupled with a transformer core to secondary windings 58' and 60'.

The primary windings 58 of the first transformer t_1 couple the output voltage of apparatus 10 to the secondary windings 58'. The primary windings 60 of the second transformer t_2 couple the output current of ablation apparatus 10 to the secondary windings 60'.

Measuring circuits determine the root mean square (RMS) values or magnitudes of the current and voltage. These values, represented as voltages, are inputted to a diving circuit D to geometrically calculate, by dividing the RMS

art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

7. The apparatus of claim 1, wherein the first and second electrode means are configured to minimize damage to a cartilage bed underlying the fibrillated cartilage surface.

8. The apparatus of claim 7, further comprising:

a sensor means positioned at the distal end of the probe means.

9. The apparatus of claim 1, further comprising:

a thermal energy source means coupled to the cabling means.

10. The apparatus of claim 1, wherein the thermal energy source is selected from RF, microwave, resistive heating, ultrasound, coherent or incoherent light and a liquid thermal jet.

11. The apparatus of claim 1, wherein the distal end of the probe means is sized to contract a joint.

12. The apparatus of claim 1, wherein the distal end of the probe means is sized to contract an articulated joint.

13. The apparatus of claim 9, further comprising:

a sensor means positioned at the distal end of the probe means;

a comparator means configured for comparing a measured temperature value at the sensor means with a predetermined temperature value and generating a disabling signal if the measured temperature value exceeds the predetermined maximum temperature value; and

a communication means for communicating the disabling signal to the thermal energy source means to cease further delivery of energy from the thermal energy source means to the first electrode means.

17. The apparatus of claim 16, further comprising:

a thermal energy source means coupled to the first electrode means.

18. The apparatus of claim 17, wherein the thermal energy source is selected from RF, microwave, resistive heating, ultrasound, coherent or incoherent light and a liquid thermal jet.

19. The apparatus of claim 17, wherein the thermal energy source means is coupled to the second electrode means.

20. The apparatus of claim 16, wherein the distal end of the probe means is sized to contract a joint.

21. The apparatus of claim 16, wherein the distal end of the probe means is sized to contract an articulated joint.

22. The apparatus of claim 16, wherein the first electrode means is formed on a periphery of a first surface of the insulator and defines a first non-conducting region between the first electrode means.

23. The apparatus of claim 22, wherein the second electrode means is formed on a periphery of an opposing second surface of the insulator means and defines a second non-conducting region between the second electrode means.

24. The apparatus of claim 16, wherein the first electrode means has a toroidal geometry defining a first non-conducting interior region.

25. The apparatus of claim 16, wherein the first electrode means has a non-circular toroidal geometry defining a first non-conducting interior region.

34. The apparatus of claim 22, wherein a first sensor means is positioned at the first non-conducting interior region.

35. The apparatus of claim 23, wherein a second sensor means is positioned at the second non-conducting interior region.

36. The apparatus of claim 16, wherein at least a portion of the probe means is malleable.

37. The apparatus of claim 16, wherein the first and second electrode means operate in a bipolar mode.

38. The apparatus of claim 16, wherein the first and second electrode means operate in a monopolar mode.

39. The apparatus of claim 17, further comprising:

a sensor means positioned at the distal end of the probe means;

a comparator means for comparing a measured temperature value at the sensor means with a predetermined temperature value and generating a disabling signal if the measured temperature value exceeds the predetermined maximum temperature value; and

a communication means for communicating the disabling signal to the thermal energy source means to cease further delivery of energy from the thermal energy source means to the first electrode means.

40. A method for modifying a geometry of a fibrillated cartilage surface, comprising:

providing a thermal energy delivery device including a probe means with a distal end and a thermal energy delivery surface;

47. The method of claim 40, further comprising:

measuring a temperature of an area adjacent to the fibrillated cartilage surface with a sensor;

comparing a measured temperature at the area adjacent to the fibrillated cartilage surface to a predetermined temperature value and generate a signal representative of a difference between the measured temperature and the predetermined temperature value; and

transmitting to the thermal energy source a signal to cease further thermal energy delivery if the measured temperature exceeds the predetermined temperature.

48. The method of claim 40, wherein the thermal energy source is an RF source.

49. The method of claim 40, wherein the thermal energy source is a microwave source.

50. The method of claim 40, wherein the thermal energy source is a resistive heating source.

51. The method of claim 40, wherein the thermal energy source is an ultrasonic source.

52. The method of claim 40, wherein the thermal energy source is a coherent or incoherent light source.

53. The method of claim 40, wherein the thermal energy source is a liquid thermal jet source.

59. The method of claim 58, wherein a melting of at least a portion of a plurality of cartilage strands creates a smoothened cartilage joint surface.

60. The method of claim 54, wherein the thermal energy delivery surface remains distanced from the fibrillated cartilage joint surface.

61. The method of claim 54, further comprising:

measuring a temperature of an area adjacent to the fibrillated cartilage joint surface with a sensor;

comparing a measured temperature at the area adjacent to the fibrillated cartilage joint surface to a predetermined temperature value and generate a signal representative of a difference between the measured temperature and the predetermined temperature value; and

transmitting to the thermal energy source a signal to cease further thermal energy delivery if the measured temperature exceeds the predetermined temperature.

62. A method for treating chondromalacia on a joint surface, comprising:

providing a thermal energy delivery device including a probe means with a distal end and a thermal energy delivery surface;

providing a thermal energy source coupled to the thermal energy delivery surface;

positioning the thermal energy delivery surface on a fibrillated cartilage joint surface; and

delivering sufficient thermal energy from the thermal energy delivery device to reduce a level of fibrillation of the fibrillated cartilage joint surface.

63. A method for treating chondromalacia on a joint surface, comprising:

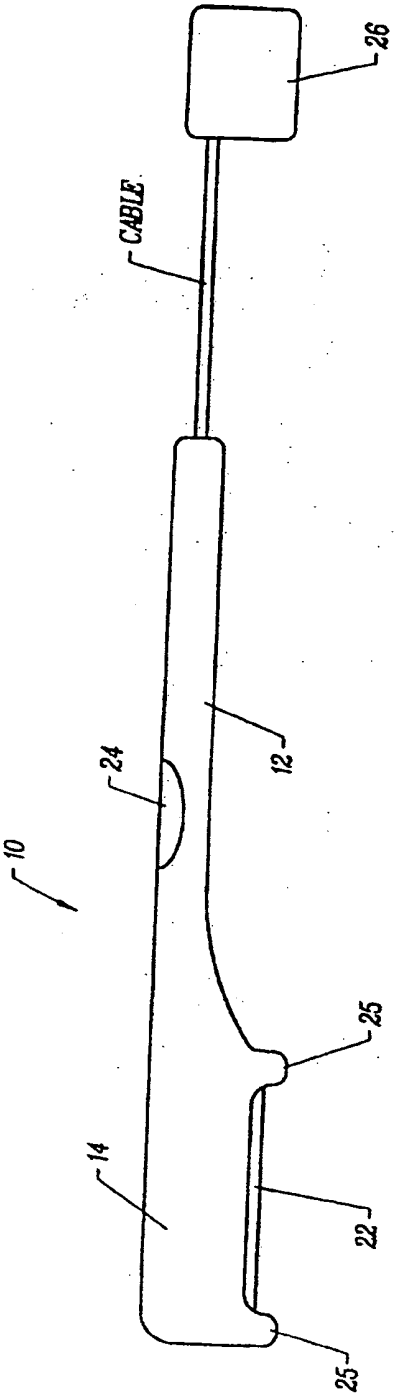


FIG. 1

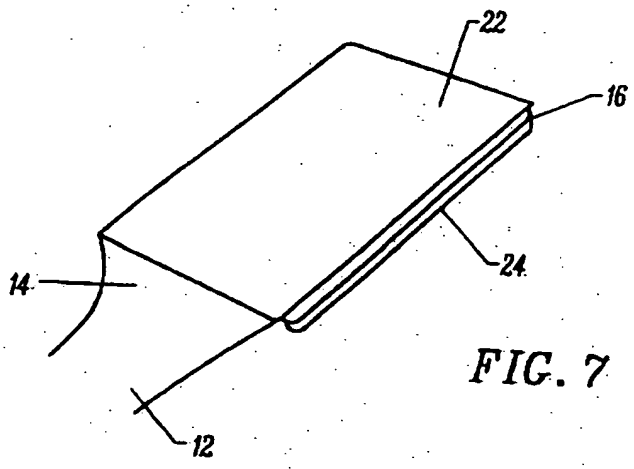


FIG. 7

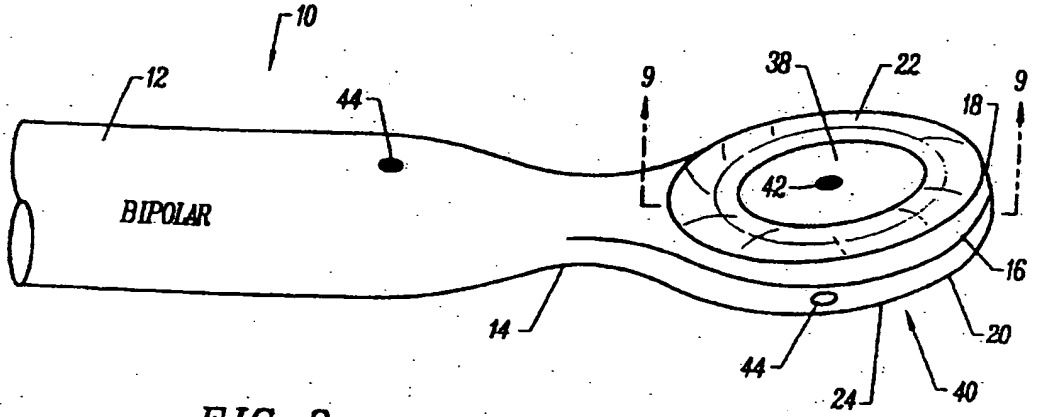


FIG. 8

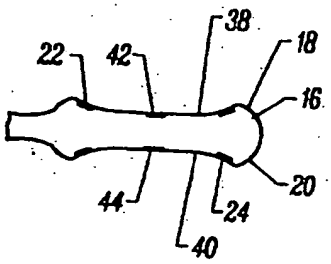


FIG. 9

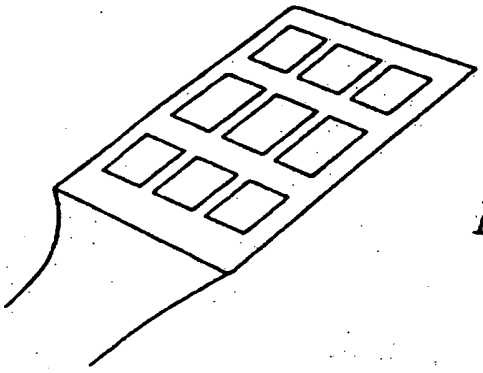


FIG. 13

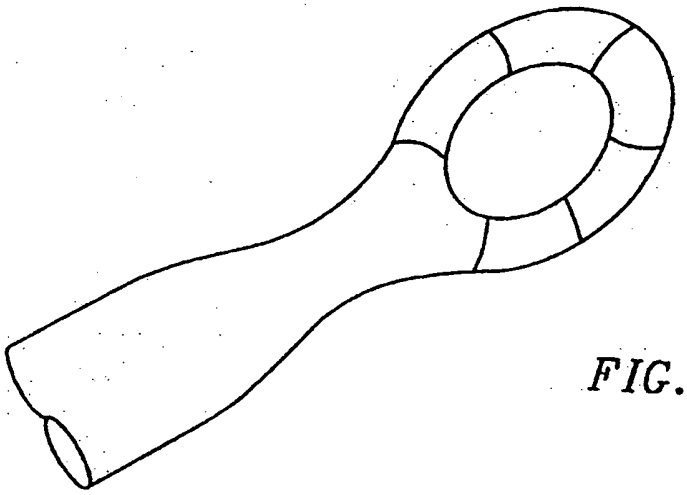


FIG. 14

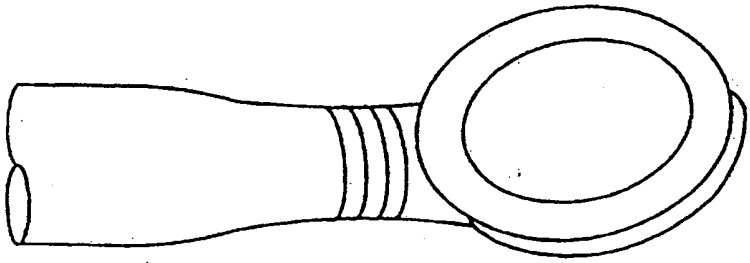
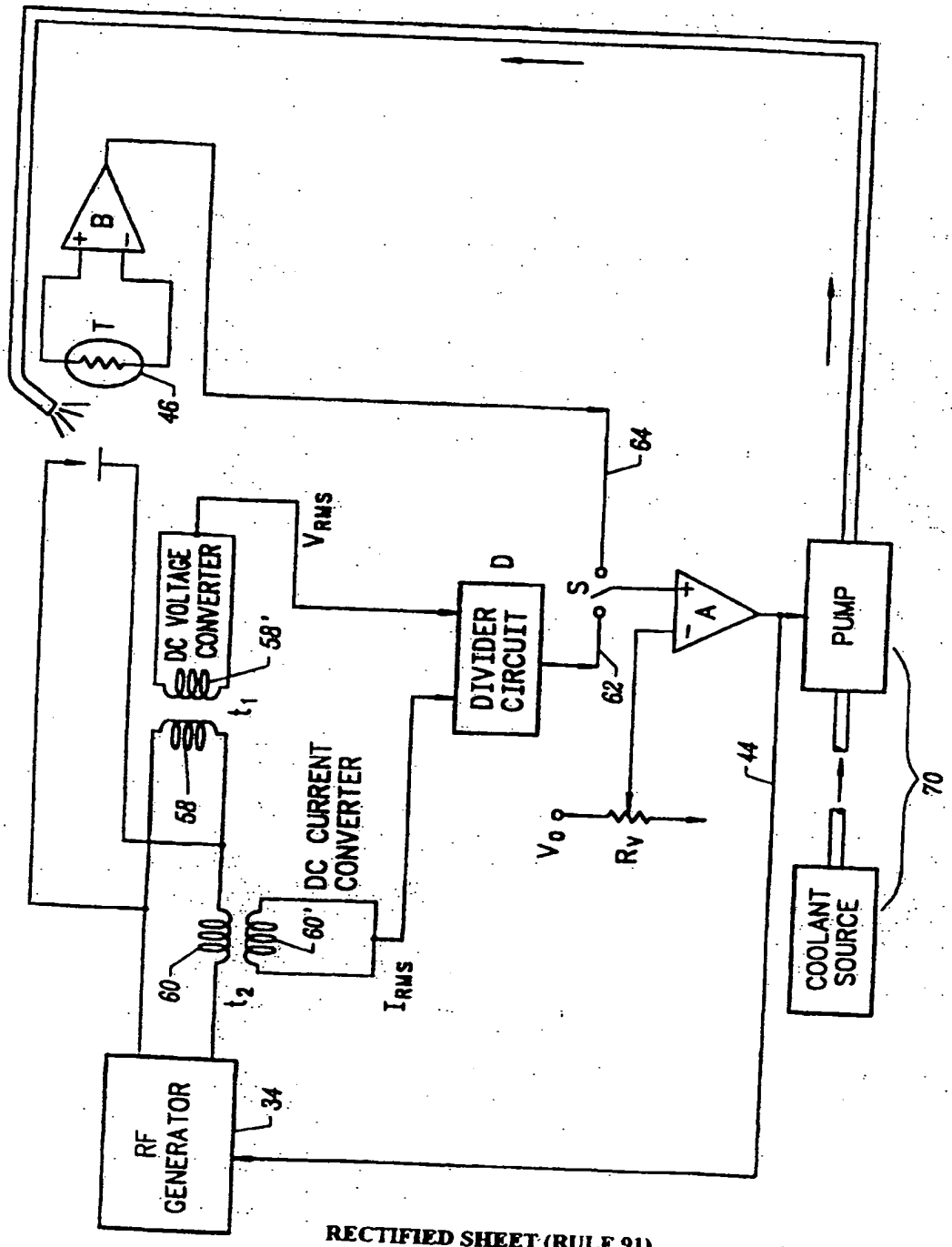


FIG. 15

FIG. 17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RF GENERATOR
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INTERNATIONAL SEARCH REPORT

In. ational application No.
PCT/US 97/13044

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 40-63
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentances of Rule6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee. this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently. this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.